

REMARKS

This is in response to the Office Action mailed on June 8, 2006, in which claims 14, 15, 17-19, and 29-33 were rejected under 35 U.S.C. § 102(b) as being unpatentable by Yokokoji et al. (U.S. Pat. No. 4,212,299) in view of Herbert (US Pat. No. 4,561,110 and claims 23-26 and 34-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. in view of Herbert and further in view of Leunberger (U.S. Pat. No. 5,314,421). The Examiner also responded to Applicant's arguments. In reliance on the following remarks, the present application with pending claims 14, 15, 17-19, 23-26, and 28-38 is in condition for allowance, and reconsideration and notice to that effect is respectfully requested.

In the Office Action, independent claims 14 and 23 were rejected under 35 U.S.C. § 102(b) as being unpatentable over Yokokoji et al. in view of Herbert. Claims 23-26 and 34-38 were also rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. and Herbert and further in view of Leunberger. These rejections will be addressed collectively. As set forth in the MPEP, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference" (MPEP 2131). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (See MPEP 2142).

Claim 14 requires an apparatus comprising a pyrogen-free sterilized bag, wherein the pyrogen-free sterilized bag has been heated to at least approximately 253° Celsius for at least approximately 30 minutes for sterilization and pyrogen removal. Claim 23 requires a kit comprising a pyrogen-free sterilized bag, wherein the pyrogen-free sterilized bag has been heated to at least

approximately 253° Celsius for at least approximately 30 minutes for sterilization and pyrogen removal. Yokokoji et al. and Herbert do not individually or in combination show, teach, or suggest a pyrogen-free (i.e., free of bacterial toxin) and sterilized bag. In particular, Yokokoji et al. discloses an apparatus comprised of a polymeric film formed of PTFE, PFA, and ETFE. However, as stated on Page 3 of the Office Action sent on June 8, 2006, Yokokoji et al. do not specifically disclose a pyrogen-free bag. The Office Action turns to Herbert to fulfill this deficiency. The Office Action's reliance on the bag of Herbert, which is "generally free" of pyrogens, as a teaching of a pyrogen-free bag is misplaced. Herbert does not show, teach, or suggest a pyrogen-free bag. Rather, Herbert teaches away from such an arrangement. Herbert discloses a bag that is manufactured under clean conditions so as to be generally free of pyrogens. Herbert sterilizes a bag that is "generally free" of pyrogens by high energy radiation so that it is not necessary to undertake thermal processing. (Col. 8, lines 13-18). Herbert does not show, teach, or suggest heat treating the bag at a temperature high enough to remove pyrogens. In fact, the material that forms the bag of Herbert, EVA, would melt at such temperatures. EVA has a melting point at a temperature of 176 °F, or 80 °C. (<http://www.indianplasticportal.com/eva.html>).

By contrast, each of independent claims 14 and 23 require that the bag is heated to at least approximately 253° Celsius for at least approximately 30 minutes for sterilization and pyrogen removal. As disclosed in the specification, "A current requirement from a number of government agencies (including the Federal Drug Administration (FDA)) is that such containers are to be heated to at least 253° Celsius for at least approximately 30 minutes to one hour (to remove pyrogen there from) prior to the storage of fluids." (Para. [0002], lines 23-27; Para. [0040], lines 22-24) Because the bag has been treated at the required temperature for the requisite amount of time, "...fluids (essentially sterile and free of pyrogen) that are stored in this polymeric film-based bag stay essentially sterile and free of pyrogen." (Para. [0042], lines 6-8). Thus, the bag of claims 14 and 23 require a pyrogen-free bag that is treated at high temperatures for a predetermined period of time to guarantee no pyrogen content. Neither Yokokoji et al. nor Herbert show, teach, or suggest heating a

bag to at least 253 °C for at least approximately 30 minutes to guarantee no pyrogen content, or a bag that is pyrogen-free.

Therefore, independent claims 14 and 23 are in condition for allowance and the rejection under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. in view of Herbert should be withdrawn. Moreover, since claims 14 and 23 are in condition for allowance, the rejections to claims 15, 17-19, 24-26, and 28-38, which depend therefrom, should be withdrawn as well and claims 15, 17-19, 24-26, and 28-38 allowed.

Therefore, independent claim 23 is in condition for allowance and the rejection under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. in view of Herbert and further in view of Leunberger et al. should be withdrawn. Moreover, since claim 23 is in condition for allowance, the rejections to claims 24-26, and 34-38, which depend therefrom should be withdrawn as well and claims 24-26, and 34-38 allowed.

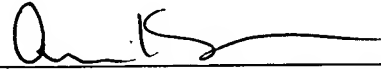
Conclusion

In view of the foregoing, pending claims 14, 15, 17-19, 23-26, and 28-38 are in condition for allowance. Notice to that effect is respectfully requested.

Respectfully submitted,

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